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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,495	04/01/2005	Bipin Chandra Muljibhai Patel	2003882-0016	4500
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CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER PERREIRA, MELISSA JEAN	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 05/22/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary	Application No. 10/500,495	Applicant(s) PATEL, BIPIN CHANDRA MULJIBHAI	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-49 and 54-83 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 12-14, 21, 22, 30-49 and 56-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 11, 15, 16, 18-20, 23-29, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/30/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-16,18-49 and 54-83 are pending in the application.
2. Applicant's election with traverse of group I, claims 1-7,11,15,16,18-20,23-29,54 and 55 and of the species a.) boron as the neutron capture element, b.) glass or glass ceramic and c.) PVP as the biocompatible outer layer in the reply filed on 3/26/09 is acknowledged. The traversal is on the ground(s) that the pharmaceutical composition of group II comprises the elected nanoparticle of group I. This is not found persuasive because the water insoluble nanoparticle of group I comprises a neutron capture element in the form of glass or a glass ceramic and a biocompatible layer (i.e. PVP) which is not included in the nanoparticle of the pharmaceutical composition of group II. The requirement is still deemed proper and is therefore made FINAL.
3. Claims 8-10,12-14,21,22,30-49 and 56-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups II-V and species there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/26/09.

Specification

4. The disclosure is objected to because of the following informalities: The brief description of drawings for Figure 1 must be corrected, since it only refers to Figure 1 and 1b in the specification; however, Figure 1 contains Figures 1A and 1B. The brief description of drawings does not address 1A. *Note, if the drawings show Figures 1A, 1B, and 1C and the brief description of the drawings refers only to Figure 1, this is an*

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error in the specification which must be corrected, rather than an application filed without all figures of drawings. See MPEP 601.01(g)[R-5]. Appropriate correction is required.

Claim Objections

5. Claim 4-7,11,15,16,8-20,23-29,54 and 55 are objected to because of the following informalities: the instant claims recite, “nanoparticle” whereas the instant claims 1-3, to which they ultimately depend, recite, “a water insoluble nanoparticle”. Appropriate correction is required for consistency.

6. Claim 3 is objected to because of the following informalities: the instant claim recites, “outer layer” whereas the instant claim 2 to which it depends recites, a “biocompatible outer layer”. Appropriate correction is required for consistency.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-7,18,20,25-28 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari (US 6,107,102).

9. Ferrari (US 6,107,102) teaches of a microstructural device or suspension of microdevices formed of iron, gold, titanium and oxides (water insoluble) or a

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biodegradable polymer material where the microstructural device may have a dimension less than about 150 nm (i.e. nanoparticle) (column 2, especially lines 60-65; column 3, lines 13-18; column 18, lines 32+). The microstructural device may have two or more layers, such as an outer hydrophilic polymer coating, such as PVP, PEG, etc. (column 2, lines 49-60; column 12, lines 9-17) which is covalently linked to the microdevice (column 5, lines 34-52). The microdevices of the disclosure may further contain boron (^{10}B)/any suitable boronated agent for BNCT, therapeutic agents (i.e. anti-cancer drugs), gadolinium (a further metal) for enhanced detectability, etc. (column 3, lines 47-49; column 8, lines 7-13; column 18, lines 9-12 and 32+). The core of the microdevice may be filled with one or more materials, such as therapeutic agents incorporated into polymer matrices (column 3, lines 23-33; column 6, lines 33-43) or may contain magnetic material (i.e. inorganic) (column 3, lines 40-43; column 19, lines 37-42; column 12, lines 35-48).

10. It is respectfully pointed out that instant claim 26 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

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11. Claims 1,4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Loyalka et al. (WO 00/45826).

Loyalka et al. (WO 00/45826) teaches of glass ceramic microspheres (i.e. 0.1 μm) containing a dopant, such as yttrium, samarium, etc. (i.e. neutron capture element) (p4, lines 30+; p6, lines 6+; p7, lines 18-24).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-7,15,16,18-20,23-29,54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari (US 6,107,102).

14. Ferrari (US 6,107,102) teaches of a microstructural device or suspension of microdevices formed of iron, gold, titanium and oxides (water insoluble) or a biodegradable polymer material where the microstructural device may have a dimension less than about 150 nm (i.e. nanoparticle) as well as that stated above (column 2, especially lines 60-65; column 3, lines 13-18; column 18, lines 32+). Ferrari does not disclose that the neutron capture element is in the form of $(\text{X-O-X})_n$, does not explicitly state that the core consists of organic polymer particles or spheres and does not disclose the amount of gadolinium (further metal) present in the microstructural device.

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15. It is respectfully pointed out that instant claim 26 is a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

16. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize any suitable boronated agent, such as in the form of $(X-O-X)_n$ as the disclosure states that boron isotope is administered in the microdevice in the form of a suitable boronated agent (Ferrari column 18, lines 32+).

17. Ferrari states that the devices contain particle/sphere containing cores (figures 4C and 7C) and therefore at the time of the invention it would have been obvious to one ordinarily skilled in the art that the therapeutic agents incorporated into polymer matrices may be in the form of particles/spheres.

18. Also, at the time of the invention it would have been obvious to one ordinarily skilled in the art to include varying amounts of gadolinium (a further metal) to tailor the microdevice for specific detection purposes and techniques (X-ray, MRI) (Ferrari column 8, lines 7-24). Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general

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conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618
/Melissa Perreira/
Examiner, Art Unit 1618